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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,686

11/03/2006

Charles Lowenstein

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2022

30743

7590

10/24/2007

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EXAMINER

MONDESI, ROBERT B

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

10/24/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/553,686

**Applicant(s)**

LOWENSTEIN ET AL.

**Examiner**

Robert B. Mondesi

**Art Unit**

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-53 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6, drawn to a fusion peptide comprising, a first sequence which promotes translocation of said fusion peptide across a membrane, and a second sequence that inhibits N-ethylmaleimide sensitive factor (NSF) activity.

Group II, claim(s) 7-13, drawn to a method of inhibiting exocytosis in a cell, comprising the step of introducing into said cell, using a fusion peptide comprising, a first sequence which promotes translocation of said fusion peptide across a membrane, and a second sequence that inhibits N-ethylmaleimide sensitive factor (NSF) activity.

Group III, claim(s) 14-25, drawn to a method of inhibiting exocytosis in a cell, comprising the step of introducing into said cell, a fusion peptide comprising, a first sequence which promotes translocation of said fusion peptide across a membrane, and a second sequence that inhibits N-ethylmaleimide sensitive factor (NSF) activity.

Group IV, claim(s) 26-32, drawn to a method of decreasing the size of myocardial infarction in a patient in need thereof, comprising the step of administering to said patient a fusion peptide comprising, a first sequence which promotes translocation of said fusion peptide across a membrane, and a second sequence that inhibits N-ethylmaleimide sensitive factor (NSF) activity.

Group V, claim(s) 33-39, drawn to a method of treating thrombosis in a patient in need thereof, comprising the step of administering to said patient a fusion peptide comprising, a first sequence which promotes translocation of said fusion peptide across a membrane, and a second sequence that inhibits N-ethylmaleimide sensitive factor (NSF) activity.

Group VI, claim(s) 40-45, drawn to a method of inhibiting exocytosis of Weibel-Palade bodies from cell, comprising the step of inhibiting NSF activity in said cell by exposing

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said NSF to a fusion peptide comprising, a first sequence which promotes translocation of said fusion peptide across a membrane, and a second sequence that inhibits N-ethylmaleimide sensitive factor (NSF) activity.

Group VII, claim(s) 46-53, drawn to a method of transferring therapeutic compounds across cellular membranes in order to treat vascular and thrombotic disorders in a patient in need thereof, comprising the step of administering to said patient a fusion peptide, wherein said fusion peptide comprises, a first sequence which promotes translocation of said fusion peptide across a membrane, and a second sequence that inhibits a cellular process that activates vascular inflammation and thrombosis.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-VII appears to be that they all relate to a fusion peptide comprising, a first sequence which promotes translocation of said fusion peptide across a membrane, and a second sequence that inhibits N-ethylmaleimide sensitive factor (NSF) activity.

However, Whiteheart et al., 1992 (cited in IDS filed July 31, 2006) disclose a fusion peptide comprising, a first sequence which promotes translocation of said fusion peptide across a membrane, and a second sequence that inhibits N-ethylmaleimide sensitive factor (NSF) activity; therefore the technical feature linking the inventions of Groups I-VII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, Groups I-VII are not so linked by the same or a corresponding special technical feature as to form a single inventive concept.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

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requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

***Restriction Requirement Applicable to all Groups***

Furthermore, the presence of multiple polypeptide sequences, each with a different SEQ ID NO: allows for a variety of patentably distinct products. Depending on the sequence of each polypeptide, the characteristics of the resulting molecule will vary in regards to structure and function. Each one of these polypeptides is capable of eliciting a specific immune response and can be used to produce a specific antibody. Therefore these polypeptides distinct absent factual evidence to the contrary. Rejoinder of all or a specified subset of the sequences is possible if Applicants provide a single and specific representative subsequence found in all or a specified subset of the sequences for search, and state that all or a specified subset of the sequences are not patentably distinct. Applicants are informed that if their specified sequence is found that all or a specified subset of sequences are obvious over that prior art sequence.

Applicant is required to elect a single SEQ ID NO: for prosecution on the merits. The applicant should be aware that selection of a single SEQ ID NO: represents a

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response to a restriction requirement of a patentably distinct product, not an election of species.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert B Mondesi/  
Primary Examiner  
Art Unit 1652  
October 18, 2007

RBM